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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant: Dennis Hechel) Group Art Unit 3737
Serial No.: 09/285,559) Examiner:
Filed: April 2, 1999) Runa S. Qaderi
THERMAL FILM) Attorney Docket
ULTRASONIC FILM DOSE) No. 3216/75036
INDICATOR)



APPEAL BRIEF

Commissioner for Patents
Washington, D.C. 20231

Sir:

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In support of the applicant's Notice of Appeal filed October 29, 2001 and appeal of the Final Office Action of July 30, 2001, the applicant responds as follows:

I. Real Party in Interest.

The real party in interest is FIBRASONICS, Inc. by assignment recorded in the U.S. Patent Office on June 15, 1999 at REEL/FRAME 010020/0982.

II. Related Appeals and Interference.

None.

III. Status of Claims.

Claims 1-11 stand rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent 4,889,122 to Watmough et al. in view

of U.S. Patent No. 4,509,533 to Chervitz. The rejection of claims 1-11 under Watmough et al. and Chervitz is appealed.

Claims 12-17 stand rejected under 35 U.S.C. §103(a) as being obvious over Watmough et al. in view of Chervitz and further in view of U.S. Patent No. 5,873,892 to Cohen. The rejection of claims 12-17 under Watmough et al., Chervitz and Cohen is appealed.

Claim 18 stands rejected under 35 U.S.C. §103(a) as being obvious over Watmough et al. in view of Chervitz and further in view of U.S. Patent No. 5,573,921 to Behnke et al. The rejection of claim 18 under Watmough et al., Chervitz and Behnke et al. is appealed.

IV. Status of Amendments.

The claims have not been amended since the final Office Action of July 30, 2001.

V. Summary of Invention.

no reference to fig. 10

The invention is drawn to a method and apparatus for applying an ultrasonic treatment to a portion of a human body. The apparatus for applying an ultrasound treatment to the portion includes means (e.g., an ultrasonic transducer) for applying ultrasound energy for the ultrasound treatment to the portion. The apparatus further includes means adapted to be disposed on the portion (e.g., a thermochromatic strip) for providing a color change only at a predetermined temperature when a dosage limit of the ultrasound treatment has been reached. An adhesive may be

provided to secure the thermochromatic strip to the portion of the human body.

VI. Issues.

Can an examiner pick and choose among diverse elements of the prior art to render obvious a claimed invention absent a recognition of the problems solved by the claimed invention?

VII. Grouping of Claims.

It is believed that the rejection of claims 1-18 is based upon the same common error. It is therefore requested that the claims be grouped together for the limited purpose of this appeal.

VIII. Argument.

A. The Rejections

With regard to claims 1-11, the Examiner asserts that "Watmough et al. disclose a means and method of applying ultrasound treatment wherein a temperature sensing visual indicator is in contact with the treated tissue, wherein temperature of the skin is indicated by color changes . . . The patent teaches a liquid crystal device that detects the temperature of the skin via color changes" (Office Action of 7/20/01, page 2). From the Examiner's statements, it may be assumed that the Examiner is suggesting that the liquid crystal device of Watmough et al. functions in the same manner as the temperature sensing device of the claimed invention.

This assumption is reinforced by the Examiner's assertion that "In this case, Watmough et al. clearly teaches a skin temperature

detector that changes color at a predetermined temperature during a ultrasound treatment" (Advisory Action of 10/31/01, page 2, 4th paragraph). Based upon these comments, the Examiner appears to have fundamentally misunderstood the teachings of Watmough et al.

For example, Watmough teaches that "the skin temperature is maintained at 42° C. (by placing a warm-water bath on the skin" (Watmough et al., col. 9, lines 51-52). More specifically, "The water maintains the skin temperature at a desired temperature, for example when treating neoplastic tissues about 42° C. in the absence of any power from the transducers" (Watmough et al., col. 5, lines 42-45). Since the water maintains the skin temperature at the desired temperature there cannot be any "color change only at a predetermined temperature when a dosage limit of the ultrasonic treatment has been reached" (claim 1, lines 7-8) under Watmough et al.

Further, since "the skin temperature is maintained at 42° C. (by placing a warm-water bath on the skin)" (Watmough et al., col. 9, lines 51-52), the temperature of the underlying tissue cannot change the surface temperature of the skin. For example, "the axial temperature distribution in tissue as a function of depth at different times is plotted in FIG. 13" (Watmough et al., col. 10, lines 7-9). FIG. 13 shows that the skin is held to a constant temperature of 42° over time (by the water bath) to a depth of about 1-1/2 cm, even though the temperature at 3 cm rises to almost 52° C. Since the skin temperature is held constant, the Watmough et al. liquid crystal device does not provide "a color change only

at a predetermined temperature when a dosage limit of the ultrasonic treatment has been reached" (claim 1, lines 7-8).

Further, the maintenance of a constant skin temperature in Watmough et al. is intentional. More to the point, the "warm water bath, which is maintained at a constant temperature, say 42° C., was placed on the patient's skin just above the treated area in order to reduce the ultrasonic power and minimize the heat loss through skin in the course of local hyperthermia treatment of superficial neoplasm" (Watmough et al., col. 9, lines 36-41). Since Watmough et al. teaches that a skin temperature should be held constant, Watmough et al. clearly teaches away from the claimed invention where skin temperature is used as an indication of a dosage limit.

The Examiner explicitly states that "Watmough et al. disclose a computer simulation for determining skin temperature" (Office Action, 7/30/01, page 2). This statement is apparently based upon the Applicant's specification, not Watmough et al., and is clearly in error.

For example, claim 8 is limited to the method step of "determining a temperature rise which the body portion will experience when a dosage limit of the ultrasonic treatment has been reached; disposing on a surface of the body portion an indicator adapted to provide a visual change only at the determined temperature; applying ultrasound to the body portion until the indicator provides the visual change at the determined temperature" (claim 8, lines 7-11). Under the invention, "The surface temperature has been found to represent the inner temperature rise

indirectly" (Specification, page 5, lines 31-33). As clearly described, the surface temperature of a body portion is an effect caused by an inner temperature distribution.

In contrast, Watmough et al. provides a "computer simulation model to simulate the effects of . . . skin temperature . . . on the temperature distribution inside the tissue during local hyperthermia" (Watmough et al., col. 5, lines 9-13). Since Watmough et al. teaches that the temperature distribution inside the tissue is an effect of skin temperature (as controlled by the water bath), Watmough et al. teaches the exact opposite of the invention. Since Watmough et al. teaches the exact opposite of the invention, Watmough et al. is a teaching away from the claimed invention.

Chervitz is of no help to the Examiner in any of these regards. Chervitz is merely a fever thermometer that provides visual changes at a number of different temperatures. There is no teaching within Chervitz of any device that provides a color or "dosage reached" message only at a predetermined temperature. As would be clear to a person of skill in the art, a device that provides a color or opacity change at a predetermined temperature would be structurally different than a device that provides visual changes at many temperatures.

For any of the above reasons, the combination of Watmough et al. and Chervitz fails to teach or suggest, *inter alia*, "means adapted to be disposed on the portion for providing a color change only at a predetermined temperature when a dosage limit of the ultrasound treatment has been reached" (claim 1, lines 6-8) or "a

thermochromatic strip adapted to be disposed on the portion and adapted to reveal a dosage reached message at a predetermined temperature when a dosage limit of the ultrasound treatment has been reached" (claim 4, lines 6-9). The combination also fails to provide any teaching or suggestion of the method steps of "determining a temperature rise which the body portion will experience when a dosage limit of the ultrasound treatment has been reached" (claim 8, lines 4-6), "disposing on a surface of the body portion an indicator adapted to provide a visual change only at the determined temperature" (claim 8, lines 7-9) or "applying ultrasound to the body portion until the indicator provides the visual change at the determined temperature" (claim 8, lines 10-11).

With regard to claims 12-17, the Examiner asserts that "Cohen teaches a thermographic or liquid crystal material with an adhesive backing provided in the front side of a pacifier flange that displays a change in color or opacity at or above a predetermined temperature" (Office Action, 7/30/01, page 5). However, as admitted by the Examiner, the Cohen thermographic or liquid crystal material is not disposed on the body portion as required by claim 12. Further, Cohen does not solve the basic problem that Watmough et al. teaches away from the invention. As such, the combination of Watmough et al., Chervitz and Cohen cannot be said to teach or suggest "means adapted to be disposed on a surface of the portion for providing an opacity change only when a dosage limit of the ultrasound treatment has been reached" (claim 12, lines 3-5).

With regard to claim 18, the Examiner asserts that "Watmough

in view of Chervitz does not teach the thermochromatic strip further comprising a tab color-coded with the threshold or predetermined temperature . . . Behnke et al. teaches an analyte test strip that displays color changes to indicate results . . . It would have been obvious . . . to further comprise the thermochromatic strip with a color comparison tab to easily observe and compare the necessary color change at the predetermined temperature" (Office Action, 7/30/01, pages 5-6).

It is noted with regard to Behnke that "The present invention pertains to an immunological process for determining an analyte . . . wherein a test strip formed of an absorbent material is used, on which an antibody is immobilized . . . a developing solution . . . is able to generate a detectable signal as a function of the amount of analyte in the sample" (Behnke et al., col. 1, lines 6-10). Since Behnke is drawn to immunological processes, it is irrelevant to thermometers. For example, since the Behnke detectable signal is a function of the amount of analyte in the sample, how does one control the amount of analyte in a thermometer?

Further, Behnke does not solve the basic problem that Watmough et al. teaches away from the invention. As such, the combination of Watmough et al., Chervitz and Behnke cannot be said to teach or suggest "a thermochromatic strip adapted to be disposed on the portion and adapted to reveal a dosage reached message at a predetermined temperature when a dosage limit of the ultrasound treatment has been reached" (claim 12, lines 3-5) or "tab color-coded with the predetermined temperature" (claim 18, lines 3-4).

B. A Prima facie Case of Obviousness Has Not Been Established

The Federal Circuit has continually held that the Examiner has the burden under 35 U.S.C. §103 of establishing a prima facie case of obviousness. In re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992); In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). This burden may be satisfied only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to the claimed invention. For example, as the Federal Circuit has held recently, as well as on numerous other occasions: "[t]here must be some reason, suggestion or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination." In re Oetiker, supra, 24 USPQ2d at 1446.

Moreover, the mere fact that the prior art references could be modified in the manner proposed by the Examiner would not have made the modification obvious unless there is some motivation or suggestion in the prior art to do so. In re Gordon, 773 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984), also see In re Fritch, 972 F.2d 1260, 23 USPQ2d 1781, 1783 (Fed. Cir. 1992) (The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification).

When making an assessment of the obviousness of the claimed invention, the prior art, viewed as a whole, must "suggest the desirability, and thus the obviousness, of making the

combination." In re Beattie, 974 F.2d 1309, 24 USPQ2d 1040 (Fed. Cir. 1992), quoting Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir. 1984). Similarly, the Examiner, under §103, must consider the claimed subject matter "as a whole". In assessing the claimed subject matter "as a whole", the results and advantages of the claimed invention must be considered. Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 7 USPQ2d 1315 (Fed. Cir. 1988); In re Chupp, 816 F.2d 643, 2 USPQ2d 143 (Fed. Cir. 1987).

It is incumbent upon the Examiner to demonstrate that the proposed combination of reference teachings is proper. Where no express teaching or suggestion is apparent from the references, the Examiner must establish, with evidence or reasoning, why one skilled in the art would have been led by the relevant teachings of the applied references to make the proposed combination. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984); ACS Hospital System, Inc. v. Montefiorde Hospital, 732 F.2d 1572, 221 USPQ 929 (Fed. Cir. 1984). When making an obviousness rejection, "[i]t is impermissible, however, simply to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template". In re Gorman, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

Applicant submits, upon a close examination of the record, that the Examiner has failed to meet the burden of establishing a prima facie case of obviousness. In general, the Examiner has completely failed to establish, with evidence or reasoning, why one skilled in the art would have been led by the

relevant teachings of the applied references to make the proposed combination. Further, the Examiner has apparently engaged in hindsight reconstruction as demonstrated by his assertion that "Watmough et al. disclose a computer simulation for determining skin temperature"; when, in fact, it is only the specification that teaches this step.

As demonstrated above, Watmough et al. teaches of the use of a water bath for purposes of maintaining a constant skin temperature. The constant skin temperature of Watmough et al. even if combined with Chervitz or Behnke would result in a device that would constantly read the same temperature under any condition of ultrasound application. As such, the various combinations of Watmough et al. and Chervitz, Watmough et al., Chervitz and Cohen et al. or Watmough et al., Chervitz and Behnke et al. each fail to teach or suggest each and every claim limitation. Since the various combinations fail to teach or suggest each and every claim limitation, the rejections are believed to be improper and should be reversed.

Further, even assuming *arguendo* that the combinations did include each and every claim element, which they do not, there is still another reason why the rejections should be reversed. Watmough et al. is directed to a system that is based upon a constant skin temperature. The Watmough et al. computer simulation model simulates the effects of skin temperature on the temperature inside the tissue, instead of *visa vera*. In order for the combination of Watmough et al. and the other various references to work as suggested by the Examiner, Watmough et al. would have to

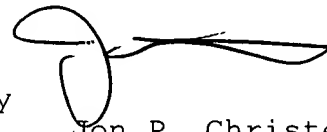
operate in a fundamentally different manner. Further, "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious". In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

For the foregoing reasons, reversal of the rejections of claims 1-18, as now presented, is believed to be in order and such action is earnestly solicited.

Respectfully submitted,

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CLAIMS

1. Apparatus for applying an ultrasound treatment to a portion of a human body, such apparatus comprising:
 - means for applying ultrasound energy for the ultrasound treatment to the portion;
 - means adapted to be disposed on the portion for providing a color change only at a predetermined temperature when a dosage limit of the ultrasound treatment has been reached; and
 - means adapted to secure the means for indicating to the portion of the human body.
2. The apparatus for applying an ultrasound treatment as in claim 1 further comprising an ultrasonic source.
3. The apparatus for applying an ultrasound treatment as in claim 1 further comprising an ultrasonic transducer coupled to the ultrasonic source.
4. Apparatus for applying an ultrasound treatment to a portion of a human body, such apparatus comprising:
 - an ultrasound transducer adapted to apply the ultrasound treatment to the portion of the human body;
 - a thermochromatic strip adapted to be disposed on the portion and adapted to reveal a dosage reached message at a predetermined temperature when a dosage limit of the ultrasound treatment has been reached; and
 - means adapted to secure the thermochromatic strip to the portion of the human body.

5. The apparatus for applying an ultrasound treatment as in claim 4 wherein the means for securing further comprise and adhesive disposed on a surface of the thermochromatic strip.

6. The apparatus for applying an ultrasound treatment as in claim 4 further comprising an ultrasonic source.

7. The apparatus for applying an ultrasound treatment as in claim 4 further comprising an ultrasonic transducer coupled to the ultrasonic source.

8. A method of applying an ultrasound treatment to a portion of a human body, such method comprising the steps of:

determining a temperature rise which the body portion will experience when a dosage limit of the ultrasound treatment has been reached;

disposing on a surface of the body portion an indicator adapted to provide a visual change only at the determined temperature;

applying ultrasound to the body portion until the indicator provides the visual change at the determined temperature.

9. The method of determining when a dosage limit has been reached as in claim 8 wherein the step of determining a temperature rise further comprises determining an ultrasound penetration depth to be achieved for the body portion.

10. The method of determining when a dosage limit has been reached as in claim 8 wherein the step of determining an ultrasound penetration depth to be achieved for the body portion further comprises selecting a frequency of the ultrasound source to achieve the ultrasound penetration depth.

11. The method of determining when a dosage limit has been reached as in claim 8 wherein the step of selecting a frequency of the ultrasound heating source further comprises determining an average depth of penetration of the ultrasound for the selected frequency.

12. Apparatus for applying an ultrasound treatment to a portion of a human body, such apparatus comprising:

means adapted to be disposed on a surface of the portion for providing an opacity change only when a dosage limit of the ultrasound treatment has been reached;

means for applying ultrasound to the body portion until the means for providing indicates that the dosage limit has been reached.

13. The apparatus for applying as in claim 12 wherein the means for applying ultrasound further comprises means for controlling an ultrasound penetration depth to be achieved for the body portion.

14. The apparatus for applying as in claim 12 wherein the means for providing the opacity change further comprises a thermochromatic strip.

15. The apparatus for applying as in claim 14 wherein the thermochromatic strip further comprises a relatively thin plastic sandwich.

16. The apparatus for applying as in claim 15 wherein the plastic sandwich further comprises a colored background.

17. The apparatus for applying as in claim 16 wherein the colored background further comprises alpha-numeric characters.

18. The apparatus for applying an ultrasound treatment as in claim 4 wherein the thermochromatic strip further comprises a tab color-coded with the predetermined temperature.